HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) HUMAN SUBJECTS RESEARCH POLICIES AND PROCEDURES

1. PURPOSE: To establish a service level policy for conducting research at the Portland VA Medical Center in accordance with the Health Insurance Portability and Accounting Act (HIPAA) of 1996. The Privacy Rule, while not intended to regulate the conduct of research, does have implications for the use of protected health information in the conduct of research. This policy will help to ensure the proper use and disclosure of VA patients protected health information (PHI) in research conducted at the Portland VA Medical Center.

2. POLICY: The HIPAA Privacy Rule becomes effective on April 14, 2003. The final modification to the rule by HHS was published on August 14, 2002 in the Federal Register (Vol. 67, No. 157, pages 53182-53273). The Portland VA Medical Center (PVAMC) Institutional Review Board (IRB) will serve as the Privacy Board for research at the PVAMC.

3. DEFINITIONS:

a. **Access-** Access is the obtaining or using of information, electronically, on paper or other medium, for the purpose of performing an official function.

b. **Business Associate -** A business associate is an individual, entity, company or organization who, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of protected health information (PHI) or provides certain services to VHA and the provision of those services involves the disclosure of PHI by VHA. Per Patricia Watts, Office of Research and Development, sponsors are generally not considered business associates because they do not perform or assist in the performance of functions

c. **Covered Entity** – The VHA is a single covered entity for the purpose of complying with the Privacy Rule. This covered entity includes all VHA hospitals and health care systems.

d. **De-identified Information** - De-identified information is health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual.

e. **Designated Record Set** – a group of records maintained by or for VHA that are the medical records and billing records; enrollment, payment, claims, adjudication, and case or medical management records; or used, in whole or part, to make decisions regarding individuals.

f. **Disclosure -** Disclosure is the release, transfer, provision of access to, or divulging in any other manner information outside VHA. The exception to this definition is when the term is used in the phrase "accounting of disclosures."

g. **Health Information -** Health information is any information created or received by a health care provider or health plan that relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or payment for the provision of health care to an individual. This encompasses information pertaining to examination, medical history, diagnosis, findings or treatment, including such information as laboratory examinations, X-rays, microscopic slides, photographs, prescriptions, etc.

h. **Individually-identifiable Information –** Individually-identifiable information is any information, including health information maintained by VHA, pertaining to an individual that also identifies the individual and, except for individually-identifiable health information, is retrieved by the individual's name or other unique identifier. Individual-identifiable health information is covered regardless of whether or not the information is retrieved by name.

i. **Individually-identifiable Health Information -** Individually-identifiable health information is a subset of health information, including demographic information collected from an individual, that is:
   (1) Created or received by a health care provider, health plan, or health care clearinghouse;
   (2) Relates to the past, present, or future condition of an individual and provision of or payment for health care; and
   (3) Identifies the individual or a reasonable basis exists to believe the information can be used to identify the individual.

   NOTE: Individually-identifiable health information does not have to be retrieved by name or other unique identifier to be covered by this Handbook.

j. **Limited Data Set.** A Limited Data Set is protected health information that excludes specific direct identifiers of the individual or of relatives, employers or household members of the individual. A limited data set is not de-identified data. A limited data set can only be used for the purposes of research, public health, or health care operations, and disclosed for the purpose of research. The use of a Limited Data Set in research requires IRB approval.

k. **Privacy Board.** "Privacy Board" is a term created by the Standards for Privacy of Individually-identifiable Health Information (45 CFR Parts 160 and 164) to describe a board comprised of members with varying backgrounds and appropriate professional competencies, as necessary, to review the effect of a research protocol on an individual's privacy rights when an Internal Review Board (IRB) does not. The Portland VA Medical Center (PVAMC) Institutional Review Board(s) (IRB) will serve as the Privacy Board(s) for research at the PVAMC.

l. **Protected Health Information (PHI).** PHI is individually-identifiable health information maintained in any form or medium. **NOTE:** PHI excludes employment records held by a covered entity in its role as an employer.

m. **Research.** For the purposes of this policy, "research" is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

n. **VHA Investigator –** A VHA Investigator must be a VHA employee (which includes official WOC employees) or contract personnel. To determine if a researcher is a VHA Investigator contact the Research Service.

o. **WOC Appointment.** A WOC appointment is a personnel appointment by which an individual contributes time to VA activities, but receives no monetary compensation.

4. RESPONSIBILITIES:

a. The **Associate Chief of Staff for Research & Development** is responsible for developing and managing policies and procedures for the creation, use and disclosure of protected health information for research purposes at the Portland VA Medical Center.

b. The **Research and Development Committee (R&D)** is responsible for the review and approval of policies and procedures regarding the creation, use and disclosure of protected health information for research purposes at the Portland VA Medical Center.

c. The **Institutional Review Board Chairperson** is responsible for reviewing and determining the appropriateness and approval for submitted requests regarding preparatory and decedent research.

d. The **Institutional Review Board** is responsible for reviewing and determining the appropriateness and approval for the creation, access, use and disclosure of protected health information in research projects submitted to the IRB for review.

e. **VHA Investigators** are responsible for:
   (1) Adhering to the policies and procedures set forth in this policy.
   (2) Adhering to the assurances signed and agreed to with any Institutional Review Board form.
   (3) Ensuring the confidentiality and protection of any VHA patient protected health information that is created, accessed, used and/or disclosed.
   (4) Ensuring that any VHA patient protected health information is not disclosed to any other person or entity, except as required by law, research oversight or as deemed acceptable by the IRB.

f. **Research Staff** are responsible for:
   (1) Adhering to the policies and procedures set forth in this policy.
   (2) Adhering to the assurances signed and agreed to with any Institutional Review Board form.
   (3) Ensuring the confidentiality and protection of any VHA patient protected health information that is created, accessed, used and/or disclosed.
   (4) Ensuring that any VHA patient protected health information is not disclosed to any other person or entity, except as required by law, research oversight or as deemed acceptable by the IRB.

5. PROCEDURES

a. **Scope of Policy**

This Policy covers all VA patients PHI, which is or may be created, used or disclosed by, through or during research activities. This policy applies to all VA employees, or appointees (including those serving without compensation), and contract personnel at VA facilities and approved off-site locations who conduct research, assist in the performance of research, or otherwise use or disclose PHI in connection with research activities at the PVAMC. In most

cases, the prior review and approval of the IRB will be required in the implementation of this Policy.

If a research activity conducted by a Portland VA Medical Center VA Investigator includes the use of protected health information (PHI), the PVAMC IRB must approve use of this information. All PVAMC VA investigators conducting PVAMC IRB approved research must obtain authority to use PHI from the potential research subject either in a separate written authorization or an authorization that has been incorporated into a research consent document unless the IRB waives the requirement for an authorization or unless otherwise stated in this policy.

b. **Privacy Board for Research**

The Portland VA Medical Center (PVAMC) Institutional Review Board(s) (IRB) will serve as the Privacy Board(s) for research conducted at the PVAMC. If the PVAMC is to use or disclose PHI on the basis of a waiver or an alteration of Authorization from a Privacy Board, the Board must be established in accordance with Section 164.512(i) of the Privacy Rule. The PVAMC IRB(s) meet the following provisions:

(1) Members must have varying backgrounds and appropriate professional competencies as necessary to review the effect of the research protocol on individuals' privacy rights and related interests.
(2) Each Board must have at least one member who is not affiliated with the covered entity or with any entity conducting or sponsoring the research and who is not related to any person who is affiliated with such entities.
(3) Members may not have conflicts of interest regarding the projects they review.

c. **Research Use or Disclosure of PHI With Authorization**

(1) As a general rule, a researcher must obtain an Authorization from all participants in research **prior to** the internal use or external disclosure of PHI for any research related purpose that is not otherwise permitted or required under this Policy.
(2) If the HIPAA Authorization language will be combined with the Informed Consent Form, the researcher must complete the Informed Consent Form/Authorization template and submit it to the IRB for its prior review and approval. If the HIPAA Authorization will be separate, prospective IRB approval is not required. In cases, where a research sponsor requests changes to the authorization language, prospective IRB review and approval is required.
(3) An Authorization for Research must be written in plain language, and must contain **all** of the following elements:
    (a) The identity, name, of the individual to whom the information pertains.
    (b) A specific and meaningful description of the information to be used or disclosed, (i.e. the description should be understandable to the individual; not a mere recitation of data elements understandable only to the research team). The description should be specific and the request should be limited to that information necessary to the research protocol. If HIV, sickle cell anemia, drug and/or alcohol abuse treatment information is to be disclosed this information must be specifically identified in the description.

(c) The name or other specific identification of the person(s) or class of persons or office designation(s) authorized to make disclosures of PHI and to use the PHI for research-related purposes. Because the VHA is a single covered entity, use of "VHA" as the releasing entity is acceptable.
(d) The name or other specific identification of the person(s) or class of persons or office designation(s) authorized to receive disclosures of the PHI and to use the PHI for research-related purposes;
(e) A description of each purpose of the use or disclosure;
(f) An expiration date or event that relates to the individual or the purpose of the use or disclosure. Examples of appropriate expiration date language are as follows:
    (i) The statement "end of research study" or similar language is sufficient if the authorization is for use or disclosure of individually-identifiable health information for research.
    (ii) The statement "none" or similar language is sufficient if the authorization is for the agency to use or disclose individually-identifable health information, including for the creation and maintenance of a research database or research repository.
    Note: This is the date that the use or authorization will expire.
(g) The signature of the individual, or someone with the authority to act on behalf of the individual and date signed. **Note:** if the Authorization is signed by an authorized representative, include a description of the representative's authority under Oregon and Washington State law to act for the individual);
(h) A statement that the individual may revoke the authorization in writing to the Principal Investigator except to the extent that VHA has already acted in reliance on it, and a description of how the individual may revoke the authorization. However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such Authorization before it was revoked and **EITHER**:
    (i) The exceptions to this right and description of how the individual may revoke his/her authorization **OR**
    (ii) A reference to the VHA's notice of privacy practices, if the exception information is contained there.
(i) A statement regarding the ability or inability to condition treatment on signing the authorization. Participation in a research project may be conditioned on a signed authorization, including treatment protocols (ex.: Phase III clinical trials) because the research may be dependent on the use and disclosure of PHI.
(j) A statement that individually identifiable information disclosed pursuant to the authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

(4) The individual must be provided with a copy of the signed Authorization.
(5) The original signed authorization must be turned into the Research Service with the signed informed consent form.

d. **Procedure for Signing an Authorization**

(1) Written authorization for release of information is valid when signed by:

(a) the individual.

(b) If the patient is not conscious, coherent or not competent for whatever reason, a legally recognized proxy must sign the Authorization. Oregon and Washington state laws recognize the following order of individuals capable to serve as proxies.

(i) Court appointed Guardian, or Proxy designated by Durable Power of Attorney;

(ii) Spouse;

(iii) A majority of the adult children (18 years of age or older) who can be so located;

(iv) Parent;

(v) A majority of the adult siblings (18 years of age or older) who can be so located

e. **Waiver of Authorization by IRB**

(1) In some circumstances, Research Authorizations otherwise required under this Policy may be waived or altered by the IRB, provided the following criteria are satisfied and documented:

(a) The use or disclosure of PHI involves no more than a *minimal risk to the privacy* of individuals, based on the presence of at least the following elements:

(i) An adequate plan to protect the identifiers from improper use and disclosure;

(ii) An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(iii) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by this Policy;

(b) The research could not *practicably* be conducted without the waiver or alteration; and

(c) The research could not *practicably* be conducted without access to and use of the PHI.

(2) A researcher must request a wavier of authorization by completing and submitting the form to the IRB for review. The IRB will review and determine whether or not the waiver of authorization is appropriate.

(3) The IRB shall include the following documentation about the waiver in the approval letter and IRB meeting minutes at which time the waiver was approved.

(a) Elements included in d.(1) above.

(b) A statement identifying the IRB and the date on which the alteration or waiver or authorization was approved;
(c) A statement that the IRB determined that the alteration or waiver of authorization, in whole or in part, satisfied the criteria for three criteria in the Rule;
(c) A brief description of the PHI for which use or access has been determined to be necessary by the IRB;
(e) A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited procedures and
(f) The signature of the IRB Chair(s) or Alternate Chair(s).

(4) If the waiver criteria are not met or, if there is any other reason that the waiver may not be granted, a denial memo singed by the IRB chair or alternate chair will be forwarded to the investigator. Such a denial memo will state the reason(s) for the denial.
(5) Uses and/or disclosures of PHI made pursuant to a Waiver are subject to the Minimum Necessary rules.

f. **Recruitment of Research Subjects:**

The following methods of recruitment are acceptable options for subject recruitment. These recruitment activities require prospective IRB review and approval.

(1) A PVAMC investigator may speak directly with his/her patients who may qualify for and be interested in a particular research project without an Authorization
(2) A PVAMC investigator may publish an IRB approved advertisement and potential subjects may call the designated individual directly. If any PHI will be collected during the conversation, the process must receive a waiver of authorization from the IRB. The PHI collected must be the minimum necessary for recruitment for the specific research project.
(3) All other uses and disclosures of PHI for the purpose of contacting and/or recruiting potential research participants may require a waiver of authorization.

g. **Reviews Preparatory to Research**

(1) VA researchers may access PHI without an authorization from the subject(s) for reviews preparatory to research, e.g. to design a research study or to assess the feasibility of conducting a study, however, prospective IRB approval is needed.
(2) Prior to accessing any PHI for this purpose, the VA researcher must submit a completed HIPAA: Research Preparation Application to the IRB for review.
(3) The researcher certifies in the HIPAA: Research Preparation Application that all of the following criteria are satisfied:
    (a) The use or disclosure of PHI is sought **solely** to prepare a research protocol, or to identify prospective research participants for purposes of seeking an Authorization;
    (b) The researcher shall not record or remove the PHI from the Portland VA Medical Center in the course of the review; and
    (c) The PHI for which access is sought is the minimum necessary for the preparation of the research.

(4) Non-VHA Researchers may not access VHA data for reviews preparatory to research.
(5) Uses and/or disclosures of PHI preparatory to research are subject to the Minimum Necessary Standard.
(6) Disclosures of VHA patient PHI collected during a review preparatory to research, may not occur outside the VHA.

h. **Research on Protected Health Information of Decedents**

(1) VHA researchers may use and disclose a decedent's PHI for research without an authorization from the subject(s), however, prospective IRB approval is needed.
(2) Prior to accessing any PHI for this purpose, the VHA researcher must submit a completed HIPAA: Research on Decedents' Information Application to the IRB for review.
(3) The researcher certifies in the HIPAA: Research on Decedents' Information Application that all of the following criteria are satisfied:
  (a) The use or disclosure is sought **solely** for research on the PHI of decedent(s);
  (b) The researcher has documentation, at the request of the VHA, of the death of such individuals; and
  (c) The PHI for which use or disclosure is sought is the minimum necessary for the purposes of the research.
(4) Uses and/or disclosures of PHI of decedents are subject to the Minimum Necessary Standard.

i. **Use or Disclosure of "De-Identified" Health Information**

(1) De-identified health information is exempt from HIPAA and may be used or disclosed for research purposes without an Authorization or IRB waiver.
(2) Researchers must provide documentation to the IRB, prior to the disclosure of PHI, that the health information has been de-identified by one of the following two methods:
  (a) **Statistical Method.** The IRB may determine that health information is de-identified for purposes of this Policy, if the Principal Investigator completes and submits the HIPAA: Statistical Analysis De-Identification Certification From. This form documents that a person with appropriate knowledge and experience applying generally acceptable statistical and scientific principles and methods for rendering information not individually identifiable
    i. Determines that the risk of re-identification of the data, alone or in combination with other data, is very small; and
    ii. Documents the methods and results by which the health information is de-identified, and the expert makes his/her determination of risk.
    iii. A Data Use Agreement should also be used to limit the distribution of records.
  (b) **Removal of All Identifiers.** The IRB may determine that health information is de-identified for purposes of this Policy, if the Principal Investigator completes and submits the HIPAA: Safe Harbor De-Identification Certification Form. The identifiers concerning the individual and the individual's employer, relatives and household members that **must**

be removed include: names; geographic subdivisions smaller than a state; zip codes; dates directly related to an individual; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual.

(3) **Re-identification**

(a) A VHA investigator may assign a code, or other means of record identification, in order to allow information de-identified under subparagraph i(2) (a) and (b) to be re-identified by VHA, provided that:

i. The code or other means of record identification is not derived from, or related to, information about the individual and that the code is not otherwise capable of being translated so as to identify the individual;

ii. The code, or other means of re-identification, is not used or disclosed by VHA for any other purpose; and

iii. VHA does not disclose the mechanism (e.g., algorithm or other tool) for re-identification.

(b) The code or other means of record identification is not considered one of the identifiers that must be excluded for de-identification. ***NOTE:*** *When disclosing de-identified data to non-VA entities this code needs to be removed.*

j. **Limited Data Set**

(1) A researcher may use or disclose a Limited Data Set for research purposes without an Authorization or Waiver of Authorization.

(2) A "Limited Data Set" is defined as PHI that **may include** any of the following *direct identifiers*:

(a) Town, city, State and zip code;

(b) All elements of dates directly related to an individual, including birth date, admission date, discharge date, and date of death.

(3) A Limited Data Set must **exclude all** of the following *direct identifiers* of the individual or of the individual's relatives, employers, or household members of the individual: names; postal address information *other than town or city, State, and zip code*; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; other account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images and any comparable images; and any other number, characteristic or code that could be used to identify the individual.

(4) A Limited Data Set may be used or disclosed only if there is a **Data Use Agreement** between the VHA and the recipient of the limited data set. The Data Use Agreement is intended to provide assurance of the limited use or disclosure of the information in the limited data set. The Data Use Agreement must be accompanied by the Responsible Requestor and Project Information Sheet, Form Data Access List.

(5) The Data use Agreement must specify the following:
   (a) The permitted uses and disclosures of information by the recipient, consistent with the purposes of the research;
   (b) The limits on who can use or receive the data;
   (c) That the recipient will not re-identify the data or contact the individuals; and
   (d) That the recipient will use appropriate safeguards to prevent use or disclosure of the limited data set other than as permitted by the Privacy Rue and data use agreement or as required by law.

(6) A VHA investigator may not release a limited data set from the VA entity without the prior approval of the IRB. The VHA investigator must submit a Responsible Requestor and Project Information Sheet, Data Use Agreement and Data Access List to the IRB for review and approval, prior to releasing the limited data set from the VHA.

k. **Minimum Necessary** – The Privacy Rule restricts use and disclosure of PHI. However, it does contain exceptions granting access in certain circumstances. Underlying all the exceptions, however, is the principle that any access should be limited to the minimum amount of information necessary to accomplish the intended purpose of the use or disclosure. For VHA research purposes, this standard requires a VHA researcher to evaluate the needs of his or her study and to request access only to those pieces of information that are necessary for the complete and accurate development of the research. This is advisable even if a research subject permits more information to be used or disclosed.

l. **Individual's Right to Access and Amend PHI**

(1) As a general rule, individuals who participate in research have a right to access their own PHI that is maintained in a Designated Record Set (DRS).

(2) However, individuals participating in research protocols that include treatment (ex: clinical trials) may be denied access to their PHI obtained in connection with that research protocol, **provided that**:
   (a) The PHI was obtained in the course of the research;
   (b) The individual agreed to the denial of access in the Research Authorization;
   (c) The research remains in process; and
   (d) The individual's rights to access such PHI are re-instated once the research study has ended and the Research Authorization has expired.

m. **Individual's Revocation of Research Authorization**

(1) As a general rule, an individual may revoke his/her Authorization, in writing to the Principal Investigator, at any time.

(2) The revocation will be applicable to the protocol or protocols specified by the individual.
If the individual revokes his/her authorization, he/she may not be able to continue participation in the research project(s), which he/she specifies. The revocation of authorization will not affect the individual's right as a VHA patient, if he/she is a VHA patient.

(3) However, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected about the individual in good faith pursuant to receipt of the revocation of Authorization. If the individual's information has already been combined with other peoples' information in the study, such as when numbers are averaged, or if it has been sent to the study sponsor, the investigator may continue to use it but no further information about the individual will be collected after he/she revokes his/her authorization.

(4) The Principal Investigator shall keep copies of all revocations of Authorizations for a specific protocol, and report them to the IRB at the time of continuing review.

n. **Business Associates**

(1) Business Associates who will receive VA patients' PHI must enter a Business Associate Agreement with the VHA, prior to the release of the VA patients' PHI.

(2) VHA Investigators with questions regarding whether or not a business associate agreement should be entered into with an entity, should contact the Research Service.

(3) The VHA Contracting Office will process Business Associate Agreements.

o. **Accounting of Disclosures**

(1) As a general rule, a VHA patient has a right to receive an accounting of disclosures of their PHI for research purposes that have been made over the six years prior to the request unless such disclosure was made pursuant to an Authorization, or is part of a Limited Data Set.
However, this does not include disclosures prior to April 14, 2003.

(2) The Principal Investigator must keep records of all disclosures of PHI in the following circumstances:

(a) Disclosures pursuant to an IRB waiver;
(b) Disclosures of PHI used in preparation of a research protocol; and
(c) Disclosure of a decedent's PHI used for research.

(3) If the research involves disclosure of PHI involving <50 individuals when an authorization from the subject has not been obtained. The Principal Investigator must keep an accounting of the disclosure that contains the following:

(d) Date of the disclosure
(e) Description of PHI disclosed
(f) Statement of purpose and basis of the disclosure

(g) Frequency, periodicity or number of disclosures made during the accounting period
(h) Date of last disclosure during the accounting period
(i) Name of research or person who received the PHI and address of that individual.

(4) If the research involves disclosure of PHI involving >50 individuals when an authorization from the subject has not been obtained. The individual should be provided a list of research protocols in which the individual's PHI *may have been used*. The Principal Investigator must keep an accounting of the disclosure that contains the following:

(a) The name of the protocol or other research activity;
(b) A description of the purpose of the study;
(c) The type of PHI disclosed;
(d) The timeframe during which such disclosures occurred and
(e) The name, address and telephone number of:
ii. The Entity sponsoring the research, and
iii. The researcher(s) or others to whom the data/information was disclosed.

p. **Notice of Privacy Practices**

VHA patients must receive a Notice of Privacy Practices (NPP). Many of the VHA patients will probably receive this Notice of Privacy Practice prior to participating in a research study. If a VHA patient has not received a NPP, a copy must be provided to the VHA patient.

q. **Transition Provision**

(1) Researchers may continue to use and disclose PHI created or received before and after April 13, 2003, if the researcher has obtained any one of the following prior to such date:

(a) An authorization or other express legal permission from an individual to use or disclose the PHI for research;
(b) The individual's informed consent to participate in the research; or
(c) IRB approval of a waiver of informed consent for the research.

Note, however, that a researcher must obtain an Authorization in the event informed consent is sought after April 13, 2003, even if a waiver of informed consent was obtained prior to April 13, 2003.

(2) The PVAMC IRB has approved the use of the PVAMC HIPAA Authorization Form template for us by investigators with PVAMC IRB approved research projects, during this transition period. Individual IRB approval of the PVAMC HIPAA Authorization Form is not required, unless a research study sponsor requires specific language to be added. At that time, IRB approval of the modified HIPAA Authorization Form is required.

(3) At the time of continuing review the following should occur:

(a) Research projects using an informed consent form, may either:
i. include the HIPAA Authorization elements into the informed consent form or

ii. maintain the informed consent form and HIPAA Authorization as separate documents.

(b) Research projects for which the IRB has approved a waiver of informed consent should complete the Waiver of Informed Consent/Authorization form.

5. REFERENCES: VHA Handbook 1605.1, Privacy and Release of Information
Department of Health and Human Services: Standards for Privacy of Individually Identifiable Health Information
Office of Civil Rights HIPAA Privacy Guidance Research

6. CONCURRENCES: Endorsed by the Research & Development Committee, 09/22/2003.

7. RESCISSION: HRPP: Policy & Procedure No. 6, endorsed by the R&D Committee 04/28/2003.

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

Michael P. Davey, M.D., Ph.D.
ACOS, Research & Development Service